CALIFORNIA REGIONAL WATER QUALITY CONTROL BOARD
SAN DIEGO REGION

FACT SHEET
TENTATIVE ORDER NO. R9-2003-0140
NPDES PERMIT NO. CA 0109193

WASTE DISCHARGE REQUIREMENTS
FOR
IDEC PHARMACEUTICALS CORPORATION
NEW IDEC MANUFACTURING OPERATIONS (NIMO)
SAN DIEGO COUNTY

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1. CONTACT INFORMATION

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2. BACKGROUND

On February 18, 2003, IDEC submitted a Report of Waste Discharge (RWD) for a *National Pollutant Discharge Elimination System* (NPDES) permit for 155,000 gallons per day (maximum flow rate) of combined discharges of brine and other wastes associated with water softening and purification processes and other non-industrial maintenance type activities (including cooling tower, boiler, and vapor compression stills blowdowns) at the NIMO facility in Oceanside. The waste discharges regulated under the NPDES permit will be routed to the Pacific Ocean through the Oceanside Ocean Outfall (OOO) via the Oceanside Land Outfall (OLO).

By letters dated February 28 and March 28, 2003, the Regional Board deemed IDEC's NPDES application incomplete and requested additional documentation and clarifications. IDEC submitted the requested information on April 18, 2003. The Regional Board deemed IDEC's application complete on April 24, 2003.

IDEC Pharmaceuticals Corporation (IDEC) develops targeted immunotherapies for cancer and autoimmune diseases. IDEC's corporate headquarters, research laboratories, and manufacturing operations are currently located in the North Torrey Pines area of San Diego County. In November 1997, IDEC received Federal Drug Administration (FDA) approval of a monoclonal antibody Rituxin® to treat certain forms of non-Hodgkin's lymphomas (NHL), making it the first monoclonal antibody to treat cancer in the United States. In February 2002, IDEC received FDA approval for a complimentary product to Rituxin® called ZEVALIN™. Both these drugs are proteins (antibodies) that exert their effect by binding cells within the patient's blood or lymphatic system. Rituxin® and ZEVALIN™ are both produced through biologics manufacturing methods known as fermentation.

As part of the company's strategic growth, IDEC is in the process of constructing a large-scale biologics production facility located in the City of Oceanside in North San Diego County. The new facility will be known as the New IDEC Manufacturing Operations (NIMO). The NIMO facility will be located in the Ocean Ranch Corporation Center at 1950 Corporate Center Dr, Oceanside, CA 92056. The facility site is located in Section 16, T11S, R4W, SBB&M, in the *Loma Alta Hydrologic Area* (904.10) of the *Carlsbad Hydrologic Unit* (904.00).

3. FACILITY AND MANUFACTURING PROCESS DESCRIPTIONS

A. FACILITY SITE

IDEC's NIMO site is located on approximately 90 acres on a parcel located on the east side of Corporate Center Drive between Ocean Ranch Parkway and Avenida De La Plata in the Ocean Ranch Corporate Center (see Attachment 1 for facility location map). The NIMO facility is a multi-product, biopharmaceutical manufacturing complex with 500,000 square feet of building space. The complex will consist of five buildings: manufacturing building, laboratory, office, utility building, and warehouse operations building. The manufacturing building will contain three seed trains, six fermenters, two harvest suites, and one purification suite for simultaneous production of the two main products Rituxin® and ZEVALIN™ (see Attachment 2 for facility layout diagram).

B. BIOLOGICS MANUFACTURING PROCESS

Unlike conventional drugs that are produced through chemical systhesis, protein products must be produced by living cells. Biologics manufacturing involves the large-scale culturing and purification of these special cells that can produce the desired protein product. IDEC drug substances are recombinant protein products. The mammalian cell

lines utilized during production have the ability to express high levels of the target proteins and be cultured in suspension. The steps that constitute drug manufacturing include:

(1) Cell culture production and harvesting,
(2) Recovery and purification, and
(3) Formulation.

The cell culture operation is the start of the production process. Cell culture operations are commonly referred to as fermentation operations. The cell culture/fermentation at the NIMO facility will use stainless steel vessels ranging from 7 to 4,000 gallons in working volume. Fermentation involves sequential transfer of the cell suspension from one vessel to another as cell density and volume increase. At the appropriate point in the process, the culture is terminated, and the liquid containing the target protein is harvested from the host cells.

The objective of purification is to separate the target protein from the other substances present in the liquid recovered from the cell culture operation. The purification process consists of multiple chromatographic and filtration steps. During purification a variety of buffer solutions are used.

Formulation is the final step in the drug substance manufacturing process. The primary objective of the formulation process is to dilute the drug substance into the final carrier solution. Following formulation, the purified product is held as a bulk liquid until such time that it is filled into sealed vials that will be delivered to the point of use.

4. DISCHARGE SOURCES AND WASTE CHARACTERIZATION

A. WASTEWATER FROM WATER SOFTENING, PURIFICATION, AND OTHER NON-BIOLOGICS ACTIVITIES

No wastes produced by or in conjunction with the biologics manufacturing processes (including cell culture production and harvesting, recovery and purification, and formulation) at the NIMO facility will be regulated under tentative Order No. R9-2003-0140. All wastewater produced by the biologics manufacturing processes will be discharged to the City of Oceanside's (City) sanitary sewer system

Tentative Order No. R9-2003-0140 regulates the discharge of 155,000 gallons per day (maximum flow rate) of combined discharges from water softening and purification processes and other non-biologics maintenance activities (including cooling tower, boiler, and vapor compression stills blowdowns) at the NIMO facility. The wastestreams associated with these processes and activities and flow-rates are listed below in Table 1 (see Attachment 3 for wastewater flow diagram):

Table 1: Brine/Wastewater Stream Descriptions and Flow Rates

Wastewater Stream Description	Maximum Flow (Gallons Per Day, GPD)
1. Primary City Water Treatment:	
Triplex Multimedia Filter – backwash/rinse water discharges	26,000
Triplex Softener – backwash/rinse water discharges and resin regeneration brine discharges	27,000
2. Pretreatment of Water for Injection (WFI) :	
Simplex Softener – backwash/rinse water discharges and resin regeneration brine discharges	9,500
Simplex Carbon Filter – backwash/rinse water discharges	2,250
3. Pretreatment of Boiler Water:	
Duplex Softener - backwash/rinse water discharges and resin regeneration brine discharges	7,500
4. Boiler Blowdown	5,700
5. Vapor Compression Stills Blowdown	21,500
6.. Cooling Towers Blowdown	55,000
7. Clean Steam Generator Test Flows	300
Total Maximum Flows Regulated Under Order No. R9-2003-0140	≈155,000 GPD

A description of the processes and activities regulated under tentative Order No. R9-2003-0140 and characterization of wastewater generated from these activities is discussed below:

(1) Primary City Water Treatment

The sources of wastewater generated from the primary City water treatment include backwashing and rinsing of the triplex multimedia filter (MMF) and triplex softener unit serving the primary city water treatment train. A brine waste is also generated from the regeneration of the softener resin with a concentrated brine solution. A total of approximately 26,000 gpd of wastewater will be generated from the backwashing and rinsing of the MMF. A total of approximately 27,000 gpd of brine and wastewater will be generated from the triplex softener unit backwashing, softener regeneration, and rinsing processes. IDEC has submitted softener regenerate waste brine test data for representative sampling conducted at its San Diego (Torreyana) facility. The water purification and softening processes and associated discharges at the Torreyana facility are similar to the NIMO site. The test data indicates that all priority metals including copper, zinc, aluminum, chromium, and nickel were found to be in non-detectable

quantities. A 96-hour static bioassay (toxicity) test conducted on the brine solution, using standard marine test species, indicated a 100 percent survival rate. The TDS found in the waste brine includes high levels of sodium (10,600 mg/l), calcium (820 mg/l), and magnesium (382 mg/l), chlorides, and sulfates.

(2) Pretreatment of Water for Injection (WFI)

The sources of wastewater generated from the *Water for Injection* (WFI) pretreatment system include backwashing and rinsing of the simplex carbon filter and softener units serving the WFI pretreatment train and from the regeneration of the softener resin with a concentrated brine solution. The wastewater flow from the WFI includes 9,500 gpd from the softening units and 2,250 gpd from the carbon filters. The pollutants contained in the brine generated from the WFI pretreatment system are similar to those found in the brine from the primary City water treatment system. The pollutants include sodium, calcium, magnesium, and other salts.

Another wastestream generated from the WFI pretreatment system is from the draining of clean steam generators serving the WFI system. A small volume of water (300 gpd) is drained from the steam generators during periodic testing and maintenance activities of the units. The flow is essentially ultra clean WFI water with low TDS and TSS levels and non-detectable toxic priority pollutants. This water is combined with the waste brine flows generated from the WFI pretreatment streams.

(3) Pretreatment of Boiler Water

The sources of wastewater generated from the pretreatment of boiler water include backwashing and rinsing of the duplex softener unit serving the boiler feed water and from the regeneration of the softener resin with a concentrated brine solution.

Approximately 7,500 gpd of brine and wastewater will be released from this process. The pollutants contained in the brine waste generated from the boiler feed water-softening process are similar to those from the WFI pretreatment system (sodium, calcium, magnesium, and other salts).

(4) Cooling Towers, Boilers, and Vapor Compression Stills Blowdowns

The steam boilers, vapor compression stills, and cooling towers at the NIMO site will be subject to daily blowdowns for maintenance purposes. A total of approximately 82,200 gpd of blowdown water will be released from the boilers, vapor compression stills, and cooling towers. The temperature of the blowdown water will not exceed ambient receiving water temperatures. Isothiazolone (a biocide) will be introduced into the cooling water prior to each blowdown. The cooling tower flow will be locked up for a few minutes, allowing the microbes to fully consume the biocide. The cooling water tower drains will be opened to allow the blowdown to proceed.

By letter dated April 1, 2003, AQUATEC (the environmental services company servicing IDEC's cooling towers, boilers, and vapor compression stills) provided representative sampling data for pollutants that can be expected from the cooling tower, boiler, and vapor compression stills blowdowns at the NIMO site. The TDS in the blowdowns ranged from 2,000 to 3,000 mg/l, mainly consisting of calcium, magnesium, and sodium salts, chlorides, sulfates, carbonates, and silica.

(5) Combined Discharge Characterization

The 155,000 gpd (maximum flow rate) of discharge from the NIMO facility, covered under Tentative Order No. R9-2003-0140, will be a combination of the waste brine (softener regeneration brine, filter and softener backwash/rinse waters), cooling tower/boiler/compression stills blowdown discharges, and clean steam generator test flows. IDEC has provided representative data for softener regenerate waste brine sampling conducted at its San Diego (Torreyana) facility (*see Section 4.A.(1)*) of Fact Sheet). IDEC has also provided representative data for cooling tower, boiler, and vapor compression blowdowns sampling (see *Section 4.A.(2)*). IDEC has indicated in its RWD, that based on the representative softener regenerate waste brine and cooling tower, boiler, and vapor compression stills blowdown sampling data, and flow rates associated with each individual wastestream, the TDS of the combined waste discharge from the NIMO facility will not exceed 20,000 mg/l. The TDS in the combined discharge shall consist mainly of calcium, magnesium, and sodium salts, chlorides, sulfates, carbonates, and silica. The combined discharge may also contain trace levels of TSS, and trace metals in the City supply water such as copper, aluminum, and arsenic

B. WASTEWATER FROM BIOLOGICS MANUFACTURING PROCESSES

No wastes produced by or in conjunction with the biologics manufacturing processes (including cell culture production and harvesting, recovery and purification, and formulation) at the NIMO facility will be regulated under tentative Order No. R9-2003-0140. These wastes will not be discharged to the brine line. All wastewater produced by the biologics manufacturing processes will be discharged to the City of Oceanside's (City) sanitary sewer system. These discharges will be regulated under an Industrial Wastewater Discharge Permit issued to IDEC by the City's Water Utilities Department. IDEC has already filed an application for an Industrial Wastewater Discharge Permit with the City. The biologics manufacturing process is expected to generate approximately 141,000 gallons per day (gpd) of wastewater. The wastewater discharged from the NIMO facility to the City's sanitary sewer system will be subject to federal regulations for pretreatment including 40 CFR 403 (*General Pretreatment Regulations for Existing and New Sources of Pollution*) and 40 CFR 439.17 (*Pharmaceutical Manufacturing Point Source Category – Fermentation Products Subcategory – Pretreatment Standards for New Sources*). These pretreatment standards require IDEC to sample the wastewater for 25 federally regulated pollutants including a list of volatile organic compounds (VOCs), pH, ammonia, and cyanide, prior to discharge to the sanitary sewer system.

The primary aqueous waste generated from the biologics manufacturing process is from the cleaning of the large-scale fermentation vessels at the site. The vessels are sanitized by processes known as Clean-in-Place (CIP) and Steam-in-Place (SIP). CIP is an acid/base chemical cleaning process for removal of residual cell debris attached to the vessels. SIP uses high purity steam and is used to ensure sterility within the vessels after they have been subjected to the CIP process. Aqueous wastes are also generated from the purification process which uses a variety of buffering solutions. The fermentation and purification cleaning wastes and spent buffering solutions are routed to a pH adjustment tank for treatment with acid and alkaline solutions prior to release to the sanitary sewer system. Buffers such as urea and ethanol used in the purification process are not discharged to the sanitary sewer system. These chemicals are classified as hazardous waste and shipped off-site for disposal.

C. DESCRIPTION OF WASTE DISCHARGE CONVEYANCE SYSTEMS

The conduits and pipes conveying the waste streams identified in Table 1 will all converge to a common sampling and monitoring point at the facility. The approximate coordinates of this sampling point will be: Latitude: 33^{o} 12' 38" and Longitude: 117^{o} 17' 50" W (see Attachment 3). The samples (24-hour composites) collected at this location will be a blend of the waste brine (softener regeneration brine, filter and softener backwash/rinse waters), cooling tower/boiler/compression stills blowdown discharges, and clean steam generator test flows.

After sampling, the combined waste streams will be routed to a newly constructed 14" brine line dedicated to the NIMO site. The 14" brine line, constructed and owned by the City, will run from the NIMO site, down Corporate Center Drive South, then West on Oceanside Blvd. to Garrison Street (see Attachment 4 for brine line location). At Garrison Street, there is a valve connection that will allow the 14" brine line to tie into the City's existing 24" Oceanside Land Outfall (OLO). The discharges from the NIMO site will eventually be routed to the Oceanside Ocean Outfall (OOO) via the OOO, for disposal to the Pacific Ocean.

The design capacity of the OOO is 30 MGD (average daily flow), with a maximum rated peak day capacity of 45 MGD. The OOO is currently permitted to accept 23.4 MGD of average daily flows. These include 21 MGD of effluent from the City of Oceanside's San Luis Rey and La Salina Wastewater Treatment Plants and the Mission Basin brackish groundwater desalinization facility (Order No. 2000-11) and 2.4 MGD of waste discharges from the from Fallbrook Public Utility District's (FUPD) Treatment Plant No. 1 (Order No. 2000-12). The United States Marine Corp Base – Camp Pendleton (USMCB CP) is proposing to discharge 3.6 MGD of combined average daily flows from its four Santa Margarita River wastewater treatment plants (Plant Nos. 1, 2, 3, & 13) through the OOO (tentative Order No. R9-2003-0155). Tentative Order No. R9-2003-0155 is scheduled to be presented for the Regional Board's consideration during its August 2003 meeting.

After the NIMO site starts discharging 155,000 gpd of wastes to the OOO, the average permitted daily flows from all existing and proposed contributory sources will increase to 27.16 MGD, which is still below OOO's average daily flow design capacity of 30.0 MGD.

D. STORMWATER DISCHARGES

Storm water discharges associated with industrial activities from IDEC's NIMO site will be regulated pursuant to the *Statewide General Industrial Storm Water Permit (SWRCB Water Quality Order No. 97-03-DWQ NPDES General Permit No. CAS000001, Waste Discharge Requirements for Storm Water Associated with Industrial Activities Excluding Construction Activities*, April 17, 1997). Attachment I of the *Statewide General Industrial Storm Water Permit* includes categories of facilities that must obtain coverage under this general permit. Biopharmaceutical products manufacturing companies such as IDEC (SIC code 2836) are included in the list of categories (i.e. Category Number 2, Manufacturing Facilities with an SIC classification of 28) covered under this general permit. Additional stormwater provisions and monitoring requirements are not included in tentative Order No. R9-2003-0140.

On August 16, 2002, the SWRCB processed IDEC's Notice of Intent (NOI) to comply with the *Statewide General Industrial Storm Water Permit* and assigned the NIMO site with a WDID identification number of 937I017431. Pursuant to the General Permit, IDEC will have to prepare a *Storm Water Pollution Prevention Plan* (SWPPP) to minimize pollutants in storm water runoff from the site. The overall objectives of the SWPPP are to identify sources of pollution that effect the quality of industrial storm water discharges and authorized non-storm water discharges, and implement *Best Management Practices* (BMPs) to reduce or prevent pollutants in storm water discharges.

Potential sources and activities that may be exposed to rain water and contribute to stormwater pollution at the NIMO site include:

(1) Hazardous material delivery and storage areas.
(2) Wastewater treatment chemicals storage.
(3) Evaporation/drift and deposition from cooling towers, boilers, and chillers.
(4) Emergency generator fuel loading and storage.
(5) Oil, grease, and fuel from equipment and vehicles.
(6) Trash dumpsters.
(7) Cleaning detergents, mop buckets, and other sanitation equipment.

5. BASIS FOR WASTE DISCHARGE REQUIREMENTS

A. FEDERAL NPDES REGULATIONS

Section 402 of the federal Clean Water Act (CWA) gives the U.S. EPA the authority to issue NPDES permits for discharges into navigable waters and to prescribe conditions for such permits necessary to carry out the provisions of the CWA. In California, the U.S. EPA has delegated this authority to the State of California. The primary regulations

developed by the U.S. EPA to implement and administer the NPDES program are found in 40 CFR 122.

The IDEC NIMO site is a new industrial point source as defined in 40 CFR 122.2. The 155,000 gpd (maximum flow rate) of combined waste discharge from the NIMO site consisting of waste brine (softener regeneration brine, filter and softener backwash/rinse waters) and cooling tower/boiler/compression stills blowdowns will be conveyed to the Pacific Ocean (a navigable waterway) for disposal. This combined waste discharge has the potential of impacting the beneficial uses and quality of the receiving water of the United States and is therefore subject to NPDES permitting requirements.

According to the NPDES regulations, effluent limitations for a specific pollutant must be established by first determining the technologically based effluent limit (40 CFR 125) and water quality based effluent limit (WQBELs) (40 CFR 131) and then selecting the most stringent of the two limits for that pollutant. The technologically based effluent limits are normally extracted from established national effluent limitation guidelines (ELGs) or performance standards published by the U.S. EPA for specific processes and manufacturing operations. The processes (softener resin backwash, regeneration, rinse, and blowdowns of cooling towers and other equipment) at the NIMO site currently do not have any established national ELGs or performance standards. Therefore, pursuant to 40 CFR 125.61 effluent limits for pollutants in the discharge were established based on best professional judgment (BPJ) or WQBELs. The WQBELs assigned to certain pollutants/parameters (including Whole Effluent Toxicity (WET), grease and oil, settleable solids, turbidity, pH limits) were based on water quality objectives outlined in the Basin Plan or the Ocean Plan. Effluent limits for certain other pollutants (including TSS) were based on BPJ (utilizing a review of effluent limits assigned to similar NPDES facilities in the San Diego Region that discharge softener regeneration waste to surface waters).

The discharge specifications and monitoring requirements specified in the tentative Order site are based on BPJ and WQBELs and are expected to protect and maintain existing beneficial uses of the receiving water and ensure compliance with federal NPDES regulations.

B. CALIFORNIA ENVIRONMENTAL QUALITY ACT (CEQA)

On August 23, 1999, the City of Oceanside approved the Negative Declaration for the Master Development Plan and Master Tentative Tract Map for the Ocean Ranch Corporate Centre Project. The Negative Declaration was prepared under the California Environmental Quality Act (Public Resources Code Section 21000 et seq. The Negative Declaration is applicable to the IDEC Pharmaceuticals Corporation's NIMO facility which is located within the Ocean Ranch Corporate Centre Project and will implement a portion of the approved Ocean Ranch Corporate Centre Project Master Development Plan.

C. WATER QUALITY CONTROL PLAN, SAN DIEGO BASIN (9)

The Water Quality Control Plan, San Diego Basin (9) (Basin Plan) was adopted by the Regional Board on September 8, 1994 and approved by the State Board. Subsequent revisions to the Basin Plan have also been adopted by the Regional Board and approved by the State Board. The Basin Plan identifies the following beneficial uses of State ocean waters to be protected:

(1) Industrial service supply
(2) Navigation
(3) Water contact recreation
(4) Noncontact water recreation
(5) Commercial and sport fishing
(6) Preservation of biological habitats of special significance
(7) Rare, threatened, or endangered species
(8) Marine habitat
(9) Aquaculture
(10) Migration of aquatic organisms
(11) Spawning, reproduction, and/or early development
(12) Shellfish harvesting
(13) Wildlife habitat

The Basin Plan relies primarily on the requirements of the Ocean Plan for protection of the beneficial uses of the State ocean waters.

D. OCEAN PLAN

The State Water Resources Control Board (hereinafter State Board) adopted a revised 2001 Water Quality Control Plan for Ocean Waters of California (Ocean Plan) on November 16, 2000. The 2001 Ocean Plan was approved by USEPA on December 3, 2001. The Ocean Plan identifies the following beneficial uses of State ocean waters to be protected:

(1) Industrial water supply
(2) Navigation
(3) Water contact recreation
(4) Non-contact water recreation
(5) Ocean commercial and sport fishing
(6) Preservation and enhancement of Areas of Special Biological Significance (ASBS)
(7) Preservation of rare and endangered species
(8) Marine habitat
(9) Mariculture
(10) Fish migration
(11) Fish spawning
(12) Shellfish harvesting
(13) Aesthetic enjoyment

In order to protect these beneficial uses, the Ocean Plan establishes water quality objectives (for bacterial, physical, chemical, and biological characteristics, and for radioactivity), general requirements for management of waste discharged to the ocean, quality requirements for waste discharges (effluent quality requirements), discharge prohibitions, and general provisions.

Table A of the Ocean Plan provides effluent limitations for conventional pollutants (including grease and oil, settleable solids, turbidity, and pH). *Table B* of the Ocean Plan list water quality objectives for pollutants for protection of marine aquatic life and human health (carcinogens and noncarcinogens).

The Ocean Plan allows the use of a minimum probable initial dilution factor, Dm (expressed as parts seawater per part wastewater), for calculation of effluent limitations for the priority pollutant water quality objectives listed in Table B of the Ocean Plan. Order No. 2000-11 (City of Oceanside) and Order No. 2000-12 (FPUD), for the discharge through the OOO, include a Dm of 82. The Dm for the OOO was calculated using the Plumes model. Effluent limitations for those Orders were calculated using the Dm of 82.

In March 200l the State Water Resources Control Board (SWRCB) staff completed a revised modeling assessment of the Dm for the OOO, using the UM3 model. SWRCB staff calculated a Dm of 76 for the combined flow from FPUD and Oceanside and staff noted that the Zone of Initial Dilution (ZID) extends approximately 78 feet from each diffuser port. SWRCB staff calculated a Dm of 77 for current and proposed combined flows, which included the United States Marine Corp Base – Camp Pendleton's (USMCB CP) proposed 3.6 MGD discharge. SWRCB staff commented that the difference in dilution was less that the resolution of the model, and therefore considered the increase in flow to be "incidental and not of consequence." Considering the variability in the entry parameters and the resolution of the model, the Dm was set to 80.

After the NIMO site starts discharging 155,000 gpd of wastes to the OOO, the average permitted daily flows from all existing and proposed contributory sources will increase to 27.16 MGD, which is still below OOO's average daily flow design capacity of 30.0 MGD. The contribution of the discharge from the NIMO facility to the overall flow in the OOO is less than one percent. Furthermore, the salinity of the combined discharge from the NIMO facility is not expected to exceed 20 parts per thousand (ppt) (data contained in RWD), which is significantly lower than the salinity of sea water (generally in the 32-36 ppt range). The lower salinity (correlating to lower density) and minimal flow volume contribution (less than one percent) from the NIMO facility to the OOO, is not expected to impact operating parameters (including mixing and dispersion) of the OOO diffusers. The Dm value of 80 is considered appropriate and will be utilized for effluent limitations calculations in Tentative Order No. R9-2003-0140.

Table A Pollutants

Tentative Order No. R9-2003-0140 includes effluent limitations for all pollutants listed in *Table A* of the Ocean Plan. The maximum effluent limitation values for grease and oil, settleable solids, turbidity, and pH are consistent with those specified in *Table A*.

The Ocean Plan does not provide a specific effluent limitation value for total suspended solids (TSS). Furthermore, there are no established Effluent Limitation Guidelines (ELGs) for TSS contained in discharges from the non-biologic manufacturing processes (softener resin backwash, regeneration, rinse, and blowdowns of cooling towers and other equipment) at the NIMO site. Staff conducted a review of TSS effluent limitations contained in the NPDES permit for several facilities that discharge to the ocean in the San Diego Region. It is evident that most POTWs (including the City's La Salinas and San Luis Rey treatment plants) and industrial facilities (power plants, water softening plants etc.) are capable of achieving a monthly average TSS level of 30 mg/l and a daily maximum TSS level of 50 mg/l in their effluent. Tentative Order No. R9-2003-0140 incorporates these TSS effluent limitations, based on Best Professional Judgement (BPJ).

Table B Pollutants

As indicated in *Section 4.B* of this Fact Sheet, the combined discharge from the NIMO site is not expected to contain detectable levels of toxic metals, volatile organics, or other priority pollutants. It is however possible that trace metals such as copper, zinc, aluminum, chromium, and nickel may appear in the discharge in detectable levels from time to time due to corrosion of water and steam conveyance pipes and conduits and wear and tear of cooling tower and boiler components. Fluctuations in the concentrations of these metals are also expected as a result of minor variations in the quality of the incoming City supply water.

Tentative Order No. R9-2003-0140 does not contain effluent limitations for individual metals and priority pollutants listed in Table B (except acute and chronic toxicity), since very insignificant levels of these pollutants are expected to be present in the discharge. This is consistent with the NPDES permits for other facilities in the San Diego Region, such as *Culligan Water Conditioning of La Jolla, Inc.* (Order No. 2000-15), that discharge softener resin regeneration brine wastes and softener backwash/rinse wastes to the Pacific Ocean. Monitoring and Reporting Program (MRP) No. R9-2003-0140, however, does require that certain metals (copper, nickel, zinc, arsenic, and chromium) contained in *Table B* of the Ocean Plan to be monitored on a semiannual basis.

Although the concentrations of individual metals and priority pollutants contained in the combined discharge from the NIMO site are expected to be minimal, the synergistic effects of these chemicals may contribute to the presence of toxicity in the effluent. Tentative Order No. R9-2003-0140 includes discharge limits and semi-annual monitoring requirements for Whole Effluent Toxicity (WET) (acute and chronic). The WET limits were calculated using *Equations 1 & 2* listed in *Section C.3* (*Implementation Provisions for Table B*) of the Ocean Plan, in conjunction with a Dm value of 80. Tentative Order No. R9-2003-0140 specifies an acute toxicity limit (TUa) of 2.7 and a chronic toxicity limit (TUc) of 81.

E. RECEIVING WATER MONITORING

Tentative Monitoring and Reporting Program No. R9-2003-0140 requires extensive receiving water and sediment monitoring in the vicinity of the Oceanside Ocean Outfall

(OOO). The tentative MRP specifies that the receiving water and sediment monitoring program for the OOO may be conducted jointly by IDEC with the City of Oceanside, and any other agencies/dischargers utilizing the OOO.

Order No. 2000-11 (*Waste Discharge Requirements for the City of Oceanside San Luis Rey and La Salina Wastewater Treatment Plants Discharge to the Pacific OceanVia the Oceanside Ocean Outfall*) and Order No. 2000-12 (*Waste Discharge Requirements for the Fallbrook Public Utility District Wastewater Treatment Plant No. 1 Discharge to the Pacific Ocean via the Oceanside Ocean Outfall*) require users of the OOO to conduct extensive nearshore, offshore, and surfzone water quality monitoring of parameters, in the vicinity of the OOO. Parameters that are monitored include temperature, dissolved oxygen, pH, light transmittance, and bacteria. Monitoring of sediment for toxic metals and other priority compounds and identification and enumeration of benthic biota is also required. Furthermore, Order Nos. 2000-11 and 2000-12 also require biological monitoring of demersal fish, macroinvertebrates, and kelp beds at various monitoring stations in the vicinity of the OOO diffuser and at designated reference areas. The biological monitoring is intended to assess the populations of marine communities, bioaccumulation of toxic pollutants, and to determine weather a significant difference exists between populations near the OOO diffuser and those in the reference areas.

The receiving water and sediment monitoring requirements specified in tentative MRP No. R9-2003-0140 are similar to those specified in Order Nos. 2000-11 and 2000-12. Only those receiving water, sediment, and biological parameters that are impacted by or attributable to the discharge from the NIMO facility, are included in the tentative MRP.

The receiving water monitoring requirements will ensure that the NIMO facility, a joint user of the OOO, complies with *Receiving Water Limitations, C*, of tentative Order No. R9-2003-140.

6. NPDES RATING

Pursuant to the *NPDES Permit Rating Worksheet*, the proposed discharge from IDEC's NIMO site was found to have a point score of 62. Pursuant to U.S. EPA guidance, facilities with a point score less than 80 are designated as NPDES Minor dischargers. The NIMO site has been classified as an NPDES Minor discharger.

Pursuant to *Title 23, Section 2200* of the California Code of Regulations, the discharger has been identified as having a *Threat to Water Quality and Complexity* (TTWQ/CPLX) rating of 3/B. Furthermore, pursuant to *Subdivision 2C of Section 2200*, the discharger will be subject to an annual fee of $2,900 based on a permitted NPDES maximum discharge flow of 0.155 MGD.

7. EFFECTIVE AND EXPIRATION DATES OF TENTATIVE ORDER NO. R9-2003-0140

Tentative Order No. R9-2003-0140 becomes effective ten (10) days after its adoption provided the Regional Administrator, USEPA, has no objection. If the Regional Administrator objects to its issuance, this Order shall not become effective until such objection is withdrawn. This Order expires on August 13, 2008.

8. WRITTEN COMMENTS

Interested persons are invited to submit written comments upon these draft waste discharge requirements. Comments should be submitted either in person or by mail, during business hours, to:

John H.Robertus, Executive Officer
Attn: Industrial Compliance Unit
Regional Water Quality Control Board, San Diego Region
9174 Sky Park Court, Suite 100
San Diego, California 92123

To ensure that the Regional Board has the opportunity to fully study and consider written material, comments regarding tentative Order No. R9-2003-0140 should be received in the Regional Board's office no later than 5:00 P.M. on Wednesday, July 30, 2003. Written material submitted after 5:00 P.M. on Wednesday, August 6, 2003 will not be provided to the Regional Board members and will not be considered by the Regional Board. Oral comments will be received during the hearing on August 13, 2003.

9. PUBLIC HEARING

In accordance with 40 CFR 124.10, the RWQCB must issue a public notice whenever NPDES permits have been prepared, and that the tentative permits will be brought before the RWQCB at a public hearing. The public notice has been published in The North County Times newspaper no less than 30 days prior to the scheduled public hearing. Tentative Order No. R9-2003-0140, will be considered by the Regional Board at a public hearing beginning at 9:00 am on August 13, 2003. The location of this meeting is as follows:

Regional Water Quality Control Board
Regional Board Meeting Room
9174 Sky Park Court, Suite 100
San Diego, California 92123

10. WASTE DISCHARGE REQUIREMENT REVIEW

After the close of the public hearing, the RWQCB may adopt a final NPDES permit. Any person may petition the State Board to review the decision of the Regional Board. A petition must be sent to the Office of the Chief Counsel, State Water Resources Control Board, P.O. Box 100, Sacramento, CA 95801 within 30 days of the Regional Board public hearing.

11. ADDITIONAL INFORMATION

For additional information, interested persons may write the following address or contact Mr. Hashim Navrozali of the Regional Board at (858) 467-2981 or by email at navrh@rb9.swrcb.ca.gov.

Regional Water Quality Control Board, San Diego Region
Attn: Hashim Navrozali
9174 Sky Park Court, Suite 100
San Diego, California 92123

Copies of the applications, NPDES waste discharge requirements, and other documents (other than those that the Executive Officer maintains as confidential) are available at the RWQCB office for inspection and copying according to the following schedule (excluding holidays):

Monday and Thursday:	1:30 pm to 4:30 pm
Tuesday and Wednesday:	8:30 am to 11:30 am
	1:30 pm to 4:30 pm
Friday:	8:30 am to 11:30 pm

An electronic copy of the Fact Sheet and Order can be accessed on the Regional Board website: http://www.swrcb.ca.gov/rwqcb9/.

12. REFERENCES FOR WASTE DISCHARGE REQUIREMENTS

The following documents provide the necessary references for the basis of this NPDES permit:

(1) The Water Quality Control Plan for the San Diego Basin (9) (Basin Plan), 1994.
(2) The Code of Federal Regulations Part 40, Section 122, 131, and 136.
(3) The Clean Water Act; Sections 208, 301, 302, 303, 304, 306, 307, 402, 403, and 405.
(4) The California Code of Regulations, Title 23, Division 3 and 4.
(5) Report of Waste Discharge, NPDES Permit Application, IDEC Pharmaceuticals Corporation, NIMO, February 18, 2003.
(6) State Water Quality Control Plan for Control of Temperature in Coastal and Interstate Waters and Enclosed Bays and Estuaries of California (Thermal Plan).
(7) Water Quality Control Plan, Ocean Waters of California, California Ocean Plan (Ocean Plan), 2001.
(8) Order No. 2000-11, *Waste Discharge Requirements for the City of Oceanside, San Luis Rey & La Salina Wastewater Treatment Plants, Discharge to the Pacific Ocean Via the Oceanside Ocean Outfall.*

ATTACHMENT 1

IDEC (NIMO) SITE LOCATION MAP

ATTACHMENT 2

FACILITY LAYOUT DIAGRAM

ATTACHMENT 3

WASTEWATER/BRINE FLOW DIAGRAM

ATTACHMENT 4

LOCATIONS OF THE IDEC AND CITY OF OCEANSIDE'S WASTEWATER/BRINE LINES AND OUTFALLS